

Docket No. 10806-154

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**PATENT**

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*Carlton L. Vign*

**IN THE UNITED STATES PATENT & TRADEMARK OFFICE**

Applicant: Thomas TERWEE et al : Paper No.:  
Serial No.: To be assigned : Group Art Unit:  
Filing Date: November 28, 2001 : Examiner:  
For: **Device for Use in Eye Surgery**

**PRELIMINARY AMENDMENT**

Box Patent Application  
U.S. Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202

Dear Sir:

Prior to calculation of the filing fee and first action by the Examiner, please amend the present application as follows:

**In the Claims:**

Please cancel claims 1-32.

Please amend claims 34, 36 and 42 to read as follows:

34. (Amended) A method of performing visual correction in a patient by replacing the natural lens with a lens implant comprising:

(a) excising an area of the anterior capsular bag of the eye having a sufficient size to surgically remove the natural lens;

(b) locating a sealing device comprising a flexible plug part and removable adjusting means of a size sufficient to cover said excised area with said adjusting means to a position where a peripheral anterior surface of said plug part contacts the inner posterior wall so as to sufficiently cover said excised area;

(c) delivering a lens filling material into the capsular bag by using a delivering means to temporarily displace and/or deform said plug part to admit passage into the capsular bag of said material;

(d) before removing the delivery means, introducing lens forming material into the capsular bag to an extent that said material exerts a sufficient pressure on the posterior side of the plug part to seal the excised area, so said lens material is prevented from being displaced from the capsular bag to the posterior chamber of the eye; and

(e) finalizing the lens forming process in the eye.

36. (Amended) A method according to claim 35, wherein said excised area has a largest diameter that essentially extends over the visual field.

42. (Amended) A method according to claim 41, including estimating at least one aberration of the lens to be formed in the capsular bag and selecting a sealing device having a plug part which together with said implanted lens is adapted to compensate for at least one such aberration.

Please add the following claims 44-75:

--44. (NEW) A sealing device for use in ophthalmic surgery to replace a catarctous and/or presbyopic natural lens, comprising a flexible plug part adapted to seal a capsulorhexis of a capsular bag and to admit an injection device for injecting a lens-forming





--58. (NEW) A sealing device according to claim 44, wherein the plug part is provided with a cut adapted to admit passage of a lens-forming material.--

--59. (NEW) A sealing device according to claim 58, wherein the cut is provided with an overlapping part adapted to seal the cut when the injection is completed.--

--60. (NEW) A sealing device according to claim 44 adapted to be positioned in a rhexis of about 1 mm in diameter positioned off the optical axis of the eye.--

--61. (NEW) A sealing device according to claim 44 adapted to be positioned in a rhexis of more than 1 mm in diameter positioned to include the optical axis of the eye.--

--62. (NEW) A sealing device according to claim 44 adapted to remain in the capsular bag after an intraocular lens-forming process is completed.--

--63. (NEW) A sealing device according to claim 61, wherein said plug part is optically clear.--

--64. (NEW) A sealing device according to claim 61, herein said plug part is adapted to cover the whole path of light that is admitted by the pupil.--

--65. (NEW) A sealing device according to claim 64, adapted to compensate for aberration.--

--66. (NEW) A sealing device according to claim 64, adapted to correct for error of refraction in the eye.--

--67. (NEW) A sealing device according to claim 44, adapted to be removed after the intraocular lens-forming process is completed.--

--68. (NEW) A method of obtaining visual correction subsequent to surgically removing the natural lens, comprising the steps of:

inserting a plug part of a sealing device through a capsulorhexis, said plug part being adapted to cover the capsulorhexis from the inside of the capsular bag;

adjusting the location of said plug part with an adjusting means operable from the outside of the capsular bag;

delivering a lens-forming material through the capsulorhexis into the capsular bag by using a delivering means and by displacing and/or deforming the plug part to admit the material; and

removing the delivering means from the eye, whereby the plug part retains a sealing position, thereby preventing displacement of the lens-forming liquid material from the capsular bag.--

--69. (NEW) A method according to claim 68, further comprising the step of removing the sealing device through the capsulorhexis when the lens-forming process is completed.--

--70. (NEW) A method according to claim 68, comprising the step of removing the adjusting means when the plug part seals the capsulorhexis by the influence of the lens-forming material in the capsular bag.--

--71. (NEW) A method according to claim 68, comprising the step of controlling the position of said plug part by means of the adjusting means.--

--72. (NEW) A method according to claim 68, comprising the step of delivering the lens-forming material to the capsular bag through a cut in the plug part and through the capsulorhexis.--

--73. (NEW) A method according to claim 68, further comprising measuring the error of refraction of the eye and optionally selecting a sealing device having a plug part capable of at least partially compensating for an error of refraction.--

--74. (NEW) A method according to claim 68, further comprising measuring the corneal topography of the cornea and thereby the amount of aberrations of a wavefront arriving from the cornea, and selecting a sealing device having a plug part with at least one surface that is capable of compensating for at least one such aberration.--

--75. (NEW) A method according to claim 68, including estimating at least one aberration of the lens to be formed in the capsular bag and selecting a sealing device having a plug part which is adapted, together with an implanted lens, to compensate for at least on such aberration.--

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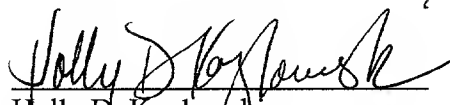
**--ABSTRACT OF THE DISCLOSURE**

A method of manufacturing an intraocular lens inside a capsular bag after the natural lens has been removed employs a sealing device comprising a plug part adapted to seal a rhexis in a capsular bag, thus preventing displacement through the rhexis of a lens-forming liquid material injected through the rhexis and adapted to replace the natural lens and form an intraocular lens implant. The plug part has a slightly larger area than the capsulorhexis and is made of a deformable polymer. The sealing device further comprises an adjusting means connected to the plug part and adapted to position the plug part to a desired location.--

### REMARKS

By the present Amendment, claims 34, 36 and 42 are amended for matters of form only. A Version With Markings Showing Changes Made is attached. Claims 1-32 are cancelled and claims 44-75 are added. Claims 44-75 contain limitations from original claims 1-32, respectively. A new Abstract in accordance with customary U.S. patent practice is also provided. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

Respectfully submitted,



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**VERSION WITH MARKINGS SHOWING CHANGES MADE**

**In the Claims:**

Claims 34, 36 and 42 are amended as follows:

34. (Amended) A method of performing visual correction in a patient by replacing the natural lens with a lens implant comprising:

(a) excising an area of the anterior capsular bag of the eye having a sufficient size to surgically remove the natural lens;

(b) locating a sealing device comprising a flexible plug part and removable adjusting means of a size sufficient to cover said excised area with said adjusting means to a position where a peripheral anterior surface of said plug part contacts the inner [(|posterior|)] wall so as to sufficiently cover said excised area;

(c) delivering a lens filling material into the capsular [a] bag by using a delivering means to temporarily displace and/or deform said plug part to admit passage into the capsular bag of said material;

(d) before removing the delivery means, introducing lens forming material into the capsular bag to an extent that said material exerts a sufficient pressure on the posterior side of the plug part to seal the excised area, so said lens material is prevented from being displaced from the capsular bag to the posterior chamber of the eye; and

(e) finalizing the lens forming process in the eye.

36. (Amended) A method according to claim 35, wherein said excised area has a largest diameter that essentially extends over the visual [filed] field.

42. (Amended) A method according to [any of] claim 41, including estimating at least one aberration of the lens to be formed in the capsular bag and selecting a sealing device having a plug part which together with said implanted lens [can] is adapted to compensate for at least [on] one such aberration.

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